Phase I Cancer Trial – Therapeutic Misconception

Category: Clinical Research, Basic Science

Roles:
- Research Investigator
- Cancer Patient
- Patient’s Spouse/Partner (optional)

Background Information:
The research study has NIH funding to conduct a phase 1 trial of a new chemotherapeutic agent to treat colon cancer. The purpose of a phase I trial is to discover the maximum tolerated dose of the agent in humans. Participants in the trial are assigned randomly to dosage, which range from sub-therapeutic to high enough to cause potentially severe side effects. Although animal studies showed some total remissions, without knowing the effective or a safe dose, the agent is estimated to have less than 5% probability of even temporary benefit. The risks of the untested agent exceed those of standard chemotherapy and the chance of severe adverse effect is probably much greater than 5%. The research is only used on those who have already tried standard chemotherapy with no success.

Research Investigator:
I am in the clinic and I interview a 63-year old retired engineer with advanced colon cancer who seems eager to enroll in the trial. I’ve already gone of the risks, purpose, design etc. and I’m now seeing him/her/them to answer questions and see if she/he wishes to join the trial.

1 These scenarios have been adapted from Horng and Grady, “Misunderstanding in Clinical Research: Distinguishing Therapeutic Misconception, Therapeutic Misestimation, & Therapeutic Optimism,” IRB, Jan-Feb 2003, pp.11-16.
Cancer Patient:

I am a 63-year-old retired engineer with advanced colon cancer who has gone through extensive cancer treatment and I am eager to participate in the trial. I have been treated with standard chemotherapy, and my cancer is advancing. I was approached in the clinic by a researcher recruiting volunteers for a trial testing the effects of a new chemotherapy on my cancer. I believe that the purpose of the trial is to find out how well the chemotherapy will shrink my tumor, that the trial is designed to help people who have no other options, and that the research doctors have my best interests in mind by offering this “cutting edge treatment.” I also believe that the risk of the untested agent is no worse than the treatment I have already tried. I estimate that probability of benefit to be at least 30%. I feel lucky that I am at an institution that offers this novel treatment.

Patient’s Spouse:

I have been married to my spouse for 35 years, and am present during the pre-enrollment interview. We were approached in the clinic by a researcher recruiting volunteers for a trial that I think is testing the effects of some type of chemotherapy on my spouse’s tumor. I have some misgivings about my spouse’s enrollment in the trial because s/he suffered through chemotherapy already. It seems to me that the trial may not be of much use to my spouse at this stage of the disease. I have always deferred to my spouse in making big decisions, but I want to understand more about the trial from the investigator.
Phase I Cancer Trial – Therapeutic Misconception: Roles

Research Investigator:
The research study has NIH funding to conduct a phase I trial of a new chemotherapeutic agent to treat colon cancer. The purpose of a phase I trial is to discover the maximum tolerated dose of the agent in humans. Participants in the trial are assigned randomly to dosage, which range from sub-therapeutic to high enough to cause potentially severe side effects. The agent is estimated to have less than 5% probability of even temporary benefit based on previous meta-analyses of similar phase I cancer trials. The risks of the untested agent exceed those of standard chemotherapy and the chance of severe adverse effect is probably much greater than 5%. The research is only used on those who have tried standard chemotherapy with no success.

I am in the clinic and I interview a 63-year old retired engineer with advanced colon cancer who seems eager to enroll in the trial. I’ve already gone of the risks, purpose, design etc. and I’m now seeing him/her/them to answer questions and see if she/he wishes to join the trial.

Phase I Cancer Trial – Therapeutic Misconception: Roles

Cancer Patient:
I am a 63-year-old retired engineer with advanced colon cancer very eager to participate in the trial. I have been treated with standard chemotherapy, and my cancer is advancing. I was approached in the oncologist office by a researcher recruiting volunteers for a trial testing the effects of a new chemotherapy on my cancer. I believe that the purpose of the trial is to find out how well the chemotherapy will shrink my tumor, that the trial is designed to help people who have no other options, and that the research doctors have my best interests in mind by offering this “cutting edge treatment.” I also believe that the risk of the untested agent is no worse than the treatment I have already tried. I estimate that probability of benefit to be at least 30%. I feel lucky that I am at an institution that offers this novel treatment.

*Imagine you are the potential participant and that you will need, at the conclusion of your exchange with the researcher, to decide whether or not to participate. Which decision you make is up to you.*

Phase I Cancer Trial – Therapeutic Misconception: Roles
**Patient’s Spouse:**

I have been married to my spouse for 35 years, and am present during the pre-enrollment interview. We were approached in the oncologist office by a researcher recruiting volunteers for a trial that I think is testing the effects of some type of chemotherapy on my spouse’s tumor. I have some misgivings about my spouse’s enrollment in the trial because s/he suffered through chemotherapy already. It seems to me that the trial may not be of much use to my spouse at this stage of the disease. I have always deferred to my spouse in making big decisions, but I want to understand more about the trial from the investigator.

*Imagine you are the potential participant and that you will need, at the conclusion of your exchange with the researcher, to decide whether or not to participate. Which decision you make is up to you.*